UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,649	09/29/2005	Yechezkel Barenholz	BARENHOLZ9A	5688

1444 7590 03/26/2010

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
SHOMER, ISAAC	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,649	BARENHOLZ ET AL.	
	Examiner	Art Unit	
	ISAAC SHOMER	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8,10,11,13,14,16-20 and 26* is/are pending in the application.

4a) Of the above claim(s) *17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8,10,11,13,14,16 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *27 July 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 23 December 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claim 14 is objected to because of the following informalities: Claim 14, as currently amended, recites "wherein said liposome forming lipid comprises a phospholipid." This is objected to because, as it appears to the examiner, a lipid cannot comprise another lipid, as a lipid is a lipid. The examiner suggests amending the claim to read "wherein said liposome forming lipid ~~comprises~~ is a phospholipid."

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 5, 10, 14, 16, and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wei et al. (US 5,677,337) as evidenced by Kumar et al. (PNAS, Vol. 68, January 1991, pp. 444-448).

In applicant's arguments dated 23 January 2009 (hereafter referred to as applicant's arguments), applicant objects to the examiner's statement "without proof" that stability for six months would be an expected property of a lipid assembly consisting of a ceramide and a pegylated lipid, as of applicant's arguments, page 14, last paragraph. In applicant's arguments, page 15, top half of page, applicant further objects to the fact that the examiner pointed to applicant's specification (as of, for example, page 9 top paragraph, page 9 third paragraph, and page 10, second full paragraph of Examiner's Action dated 23 July 2009, hereafter referred to as Examiner's Action), stating that the examiner has used applicants own specification to make the invention obvious. Applicant cites In re Ruff, 118 USPQ 340, 347 (CCPA 1958) to back up this point. Applicant further argues that the present invention has shown unexpected results, as of applicant's arguments, page 15, last sentence.

In response to applicant's argument that the examiner has not shown proof that a lipid assembly as taught by Wei would have been stable for at least six months, the examiner reminds applicant that an old composition does not become patentable upon the discovery of a new property. See MPEP 2112(I). This property need not be recognized at the time of the invention. See MPEP 2112(II). The liposomal preparations shown on column 15, Table 1, first and third line, consist of phosphatidylcholine, cholesterol, and C2 or C6 ceramide, which appear to read on all of the structural elements of the instant claims. Furthermore, as of MPEP 2145(II), prima facie obviousness is not rebutted by merely recognizing additional advantages or latent properties present in the prior art. Hence, the mere fact that Wei did not recognize this

property does not overcome the examiner's rejection, as applicant has not pointed out a structural difference between the prior art and the instant claims.

In response to applicant's arguments regarding examiner's reference to applicant's specification, the examiner notes that the fact pattern in the cited case, In re Ruff, 118 USPQ 340, 347 (CCPA 1958), is different from that of the instant application. The cited case appears to be drawn the court's reversal of an examiner's rejection, wherein the examiner stated that two chemical moieties are equivalent because applicant has disclosed them to be equivalent. As of the sentence bridging pages 343 and 344 of the cited case, "concession or admission of equivalency is predicated on the fact of appellants having *included in the same application a disclosure of both the amino and the mercap*to types of tarnish inhibitors and on having originally claimed both of these groups in generic claims."

The fact pattern cited above is not relevant to the present application. In contrast to the cited case, all of the structural elements of the claim are found in the prior art in the instantly rejected claims. What is not found in the prior art is a disclosure that the particular combination would have had the property of being storage stable for over six months, as pointed out by applicant, page 15, bottom of page. The examiner has merely pointed to applicant's specification to show that this latent property which was not acknowledged in the prior art would have been expected. See examiner's action, page 9, first paragraph. The examiner reminds applicant that something which is old does not become patentable upon the discovery of a new property, and that a *prima facie* case of

obviousness is not rebutted my merely recognizing additional advantages or latent properties in the prior art. See MPEP 2112.01(I) and MPEP 2145(II).

In response to applicant's assertion of unexpected results, the examiner notes that the applicant has not pointed to a specific location in the specification or provided additional evidence to show these unexpected results. It is the burden of applicant to show that results are unexpected, and thereby significant. See MPEP 716.02(b)(I) and 716.02(b)(II). Applicant must show the statistical and practical significance of these results. As applicant has failed to do so in the response dated 23 December 2009, the examiner will not evaluate applicant's consideration of unexpected results at this time.

Claims 6-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wei et al. (US 5,677,337) as applied to claim 5 above, and further in view of Cuvillier et al. (Nature, June 27, 1996, p. 800-803).

In applicant's response, applicant has argued that as claim 1 is patentable, claim 5 is patentable as it depends upon claim 1, as of applicant's arguments, page 16, second and third paragraphs. Applicant has argued that the Curvillier reference adds nothing to the "deficiencies" of Wei. In response, the examiner notes that claims 1 and 5 are not patentable for the reasons shown above. In response to applicant's arguments that Curvillier adds nothing to Wei, the examiner notes that one of ordinary skill in the art at the time the invention was made would have looked to Curvillier to have added N,N-Dimethylsphingosine to the lipid assembly of Wei. See examiner's action, page 11, first two paragraphs.

Claims 3, 11 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wei as applied to claim 1 above, and further in view of Nicholas et al. (Biochimica et Biophysica Acta, 1463, 2000, pp. 167-178) as evidenced by Tirosh et al. (Biophysical Journal, Vol. 74, March 1998, pp. 1371-1379).

Applicant argues that Nicholas adds nothing to the "deficiencies" of Wei, as of applicant's arguments, page 17, first full paragraph. Applicant further argues that because the lipid assemblies of taught to be more stable in blood circulation, one of ordinary skill in the art would not have expected that said combination would have been stable to storage for six months. In response, the examiner reminds applicant that a new property of a composition does not need to be shown at the time the invention was made, as of MPEP 2112(II) and MPEP 2145(II) as shown supra. Applicant's argument that said property of stability for six months is an unexpected result will not be substantively evaluated because applicant has not that results are unexpected, and thereby significant. See MPEP 716.02(b)(I) and 716.02(b)(II) as referenced above. As claim 1 is properly rejected under Wei, as shown above, claims 3, 11, and 13 are properly rejected as well.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./
Examiner, Art Unit 1612

/JEFFREY S. LUNDGREN/
Primary Examiner, Art Unit 1639